

## **REMARKS**

### **Status of the Claims**

Claims 16, 28 and 78-91 are pending in this application. Claim 28 has been withdrawn from further consideration. Claim 92 has been added, which is supported by claim 78. Thus, no new matter has been added.

In view of the following remarks, Applicants respectfully request the Examiner withdraw all rejections and allow the presently pending claims.

### **Issues under 35 U.S.C. § 103(a)**

The Examiner has rejected claims 78-80, 83 and 88-91 under 35 U.S.C. § 103(a) as being obvious over Muller (US application publication No. 2003/0059470; hereinafter “Muller”) in further view of Woo et al. (WO 02/13815; hereinafter “Woo”). Also, the Examiner has rejected claims 16 and 81-87 under 35 U.S.C. § 103(a) as being obvious over Muller.

These rejections are respectfully traversed.

In the Advisory Action, the Examiner states that

Applicants "strongly request" reconsideration of the art made of record on the grounds of the definition of the term "emulsion". Specifically, Applicants assert that since an emulsion necessitates the presence of both oily and aqueous phases that the composition of the art necessarily represents a teaching away from the instant invention. Applicants reference [0036] of Muller, it is further asserted "that the problem of solubility of paclitaxel could not be solved with the oily composition" and that the "present invention solves the same problem with a composition without changing the oily phase itself". In response, the Examiner respectfully disagrees and maintains that Muller provides clear teaching that the paclitaxel solid particles are dissolved in either the oily or aqueous phases of the prepared microemulsion [0036]. One of the compositional variants taught by the reference teaches the preparation of an oil-in-water emulsion wherein the drug can be dissolved in the oily phase and then further dispersed in an aqueous phase. Given this, it follows that an oily composition have paclitaxel dissolved therein is formed. That is, regardless of the location of the final oil/drug composition, be it alone or dispersed in water, the instantly claimed oil/drug composition is taught. Regarding Applicants' "consisting essentially of" transitional language, the Examiner has reconsidered Applicants' instant disclosure and can find no immediate discussion suggesting that the presence of water alters anything concerning the instant composition. As such, said "consisting essentially of" language is interpreted by the Examiner as having the scope of "comprising" where it pertains to additional components such as water or aqueous environments. Further support of this position is found in the instant disclosure where Applicants discuss the intended target of the instant composition as being an aqueous environment. Lastly, Applicants' attempts to distinguish the instant composition over the art are unpersuasive in light of claims 80, 86, 87 and 90 which are directed to a composition including an emulsifier. Thus, it appears that the instantly claimed composition is envisioned by Applicants as taking on an emulsion form. See also Example 1 (pg. 19 of the Spec.). For these reasons, Applicants' arguments are found unpersuasive. Said rejection is therefore maintained.

Applicants respectfully disagree with the Examiner. It is submitted that Muller does not teach or suggest any oily composition. Even if Muller prepares an oily composition, such oily composition is simply an intermediate and is not the final product intended by Muller.

Specifically, paragraphs [0011]-[0019], the Examples and the claims of Muller clearly state that a dispersion comprises an oily phase; an aqueous phase, in the form of O/W or W/O emulsion; and an active ingredient. Thus, it is obvious that Muller essentially requires emulsion of O/W or W/O.

More specifically, paragraph [0036] of Muller states that

To produce the dispersion according to the invention, the active ingredient is added to the aqueous phase or the oil phase in particle form and then all components are subjected to a fairly high- or high-energy process such as, for example, homogenization, especially high pressure homogenization. The high-energy process of high pressure homogenization leads to incorporation of the active ingredient into the emulsion by molecular dispersion, and no active ingredient crystals remain detectable in the polarization microscope. The emulsions obtained surprisingly have a stability similar to that of systems produced using organic solvents.

From the above, even if the active ingredient is added to an oily phase to form an oily composition, such intermediate oily composition of Muller is not the final composition, as intended in paragraphs [0011]-[0019] and the claims of Muller. In other words, after formation of the oily composition, such oily composition and the aqueous phase in the form of O/W or

W/O are all subjected to a homogenization, which leads to incorporation of the active ingredient into the emulsion. Therefore, it is evident that Muller achieves its intended purpose by using both aqueous phase and oily phase to prepare an intended dispersion.

In summary, Muller solves the problem by disclosing a composition in the form of a W/O or O/W emulsion. Therefore, Muller fails to teach or suggest that the problem of solubility of Paclitaxel could be solved by the composition of the present invention which is in the oily phase only, accordingly, clearly establishing the non-obviousness of the present invention over Muller. The deficiencies of Muller cannot be cured by the secondary reference of Woo. This is because Woo also discloses a composition prepared in the form of an emulsion (please see page 7, lines 2-23 of Woo).

Separately, Applicants point out that the Examiner clearly admits that Muller is deficient in teaching any ratio for any combination of mono- and tri-glycerides. The Examiner attempts to cure this deficiency by relying upon Woo. However, Applicants question the rationale that requires those of skill in the art to halt the procedure of Muller midway and make modifications to an intermediate. According to case law, "Homologous intermediates of the prior art which would not obviously have properties in common with the claimed compounds does not render the latter obvious if there is no motivation to interrupt the prior art synthesis to determine the properties possessed by the intermediates." In re Lahu et al., 747 F.2d 703, 223 USPQ 1257 (Fed. Cir. 1984).

With such case law in mind, Applicants respectfully submit that if the above essential oily phase and aqueous phase in W/O or O/W emulsion are altered to only an intermediate oily phase dispersion, as suggested by the Examiner, such oily dispersion of Muller alone would not have properties in common with the claimed composition. In other words, the essential oily and aqueous phases of Muller cannot be altered in such a way that the intended purpose (i.e., the active ingredient can only be dissolved slightly or insoluble in both phases) of Muller becomes impossible. Accordingly, there is no motivation to interrupt Muller's synthesis to determine the properties of the intermediate oily phase alone. Reconsideration is respectfully requested.

In light of the above remarks, since independent claims 78-80 of the present application are believed to overcome the 35 U.S.C. § 103(a) rejections, the dependent claims therefrom are also believed to be patentable. Accordingly, the Examiner is respectfully requested to withdraw the obviousness rejections and allow the pending application.

### **Request for Rejoinder**

Applicants hereby request that the withdrawn claim 28 be rejoined upon allowance of claim 78. Specifically, such withdrawn claim 28 includes all the limitation of claim 78. Therefore, rejoinder of claim 28 is requested upon allowance.

### **Conclusion**

In view of the above remarks, Applicants believe the application is in condition for allowance.

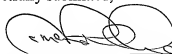
Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Craig A. McRobbie, Reg. No. 42,874 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

By



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